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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,011	02/09/2004	Margarita Ortiz-Marciales	UPR-3100	2531
24496	7590	05/12/2006	EXAMINER	
PATENT LAW OFFICES OF HEATH W. HOGLUND 256 ELEANOR ROOSEVELT STREET SAN JUAN, PR 00918			BARKER, MICHAEL P	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/775,011	<b>Applicant(s)</b> ORTIZ-MARCIALES ET AL.	
	<b>Examiner</b> Michael P. Barker	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/3/04 &amp; 6/28/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

**Claims 1-5** are pending in this application. **Claims 1-2** are rejected as being indefinite under 35 U.S.C. 112 2<sup>d</sup> ¶. **Claims 1** and **3-5** are rejected for lack of enablement under 35 U.S.C. 112 1<sup>st</sup> ¶.

#### *Information Disclosure Statement*

The information disclosure statement (IDS) submitted May 3, 2004 and June 28, 2004 were correctly filed. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements were considered by the examiner. Please refer to Applicant's copies of PTO-1449 submitted herewith.

#### *Claim Rejections - 35 USC § 112 2<sup>d</sup> ¶*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-2** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, **Claims 1-2** both recite the language, "A method of deriving. . . *as described herein*", (emphasis added). This language is interpreted as a reference to the Specification. Applicant's claims should be written to stand on their own, such that the public is informed as to what constitutes infringement of the patent. Therefore, Applicant may bring into **Claims 1-2** limitations originally described in the Specification in order to overcome this rejection or cancel **Claims 1-2** and rely on the remaining claims to define the boundaries of the invention.

***Claim Rejections - 35 USC § 112 1<sup>st</sup> ¶***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1 and 3-5** are rejected under 35 U.S.C. 112, first paragraph, because the Specification, while being enabling for a method of preparing B-alkylated oxazaborolidines from a parent oxazaborolidine compound comprising the step of alkylating the boron of the parent oxazaborolidine compound, it does not reasonably provide enablement for, “A method of deriving B-substituted oxazaborolidines having a parent boroheterocyclic compound comprising the step of performing alkylation of the parent *boraheterocyclic* compound [sic].” The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As stated in MPEP 2164.01(a), “There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue.”

*In re Wands*, set forth the following eight factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph:

1. The nature of the invention;
2. The state of the prior art;
3. The predictability or lack thereof in the art;
4. The amount of direction or guidance present;
5. The presence or absence of working examples;
6. The breadth of the claims;
7. The quantity of experimentation needed; and
8. The level of the skill in the art.

8 USPQ2d 1400 (1988).

***The nature of the invention***

The nature of the invention is a “method of deriving B-substituted oxazaborolidines having a parent boroheterocyclic compound comprising the step of performing alkylation of the parent *boraheterocyclic* compound [sic].”

***The state of the prior art and the predictability or lack thereof in the art***

The state of the prior art, organic synthesis, involves experimentation and characterization data to determine whether a hypothesized product resulted from a given reaction, as well as the quantity and purity the resulting product in order to determine the efficiency of the reaction mechanism. There is no absolute predictability even in view of the seemingly high level of skill in the art. Because of the nature of unpredictability, it is highly unlikely that the contemporary knowledge in the art would allow one of ordinary skill in this art to accept that the claimed method of preparing alkylated oxazaborolidine compounds by alkylating the boron of a parent oxazaborolidine compound to prepare all B-substituted oxazaborolidine is broad enough to encompass a method of preparing all B-substituted oxazaborolidines having a parent boroheterocyclic compound comprising the step of performing alkylation of the parent boroheterocyclic compound.

***The amount of direction or guidance present and presence or absence of working examples***

Nowhere does the Specification teach a method of generally alkylating a parent boroheterocyclic compound to prepare B-substituted oxazaborolidines. Rather, Applicant's Specification teaches a method of B-alkylation of a parent oxazaborolidine in order to prepare B-alkylated oxazaborolidines.

***The breadth of the claims, quantity of experimentation, and level of skill in the art***

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed to enable one skilled in the art to use Applicant's claimed method in preparing all B-substituted oxazaborolidines is undue. With no direction or guidance from Applicant's Specification, one of skill in the art would need to determine every possible B-substituted oxazaborolidine which can result from alkylating any position (i.e. not only alkylating the boron) of every boroheterocyclic compound.

Because of the aforementioned reasons, a person of skill in the art could not practice the claimed invention herein, or a person of skill in the art could practice the claimed invention herein only with undue experimentation and with no assurance of success.

This rejection can be overcome by amending **Claims 1 and 3** to more narrowly define the boundaries of the method taught in the Specification and . For example (suggested changes italicized):

“Claim 3: A method of *preparing B-alkylated oxazaborolidines from a parent oxazaborolidine* compound comprising the step of *alkylating* the parent *oxazaborolidine* compound.”

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to

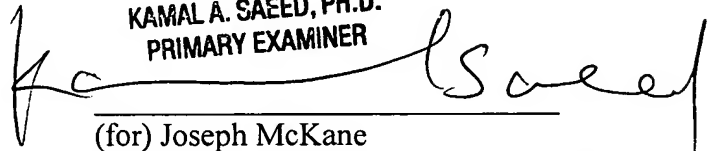
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reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.



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KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER



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